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Food Safety and Inspection Service
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Shirley A. Coffield

RE: Docket No. 04-021 ANPR: RIN 0583-AC88

Federal Measures to Mitigate BSE Risks: Considerations for Further Action

This submission is in response to a request for public comment on the Advance notice of proposed rulemaking *Federal Measures to Mitigate BSE Risks: Considerations for Further Action, (Federal Register Vol. 69, No. 134, Wednesday, July 14, pp.42288-42300)* on behalf of the North American Natural Casing Association, (NANCA) a trade association that represents the majority of natural casing producers and brokers in North America, and the International Natural Sausage Casing Association (INSCA) a trade association representing most major companies in the world producing and trading natural casings, as well as all country and regional associations. Our members produce, buy, sell, and distribute casings worldwide. The US industry processes the casings saved by slaughterhouses in the United States in addition to importing and exporting significant amounts of casings to meet domestic and global demand.

Natural casings, which are derived primarily from the intestines of hogs, sheep, and beef cattle, are used in a wide variety of high quality sausage products that constitute a significant industry in North America and throughout the world. Of the three primary types of natural casing, only beef casings are affected by this advanced notice of proposed rulemaking.

Beef Casings: The three most commonly used types of natural beef casing are beef rounds, beef middles, and beef bung caps. Beef rounds are derived from the small intestine of cattle, beef middles from the large intestine, and beef bung caps from the caecum, which connects the large and small intestines.

Beef rounds are used in a wide assortment of quality sausage products, including numerous varieties of ring bologna, knockwurst, blood sausage, and ring liver sausage, as well as specialty sausages such as mettwurst, kishka, and holsteiner. In addition, the majority of halal sausages are made using beef casings (smaller diameter halal sausages generally are made using lamb casings). Processors can substitute collagen casings for some types of sausage made from natural beef rounds, but this generally results in a lower quality product with a decreased market value.

Beef middles and beef bung caps also are used in a wide range of quality sausage products. Sausages made from beef middles include bologna, dry and semi-dry cervelats, dry and cooked salami, and veal sausage. Sausages made from beef bung caps include veal sausage, large bologna, and cooked salami.

The United States imports most beef intestines for use as natural casings from South American countries such as Brazil, Argentina, Paraguay and Uruguay, which currently are not included on the US BSE risk list. Brazil, Argentina, Paraguay, Uruguay, and other South American countries also are classified as BSE free by the European Commission, which has elaborate risk analysis programs in effect to determine BSE risk. Prior to the diagnosis of a BSE-infected animal in Canada, the United States also had imported beef casings from Canada. Currently, only limited amounts of beef intestines (none from the small intestine of animals slaughtered January 12, 2004 or later) from animals slaughtered in the United States are saved for use as natural casings. However, there has been a demand for the US product in several countries, primarily in Europe, where the US product currently is not allowed to be imported, and the growth potential for this product would be significant if trade restrictions not based on science were removed. Greater amounts of beef small intestines were saved for an edible product exported primarily to Asia (Japan and Korea) and Mexico (as *tripas*). This is an important value-added product for cattlemen and meat packers, and these exports consequently are important to our industry overall.

The manufacture of sausages from natural beef casings generates over $200 million dollars in sales every year for the North American sausage and casing industries and employs a significant number of people. The industry is committed to preserving this valuable market, while at the same time providing the public with the safest product possible.

In the notice published on July 14, 2004, FSIS requested information on issues important to our industry in questions 2 and 34, 35 and 36. Responses to those questions, including, in connection with question 2, detailed information on available methods for removing the distal ileum from bovines, follows:

I. Question 2, on pg 42296, FSIS requested information as follows: *"What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?"*

A. All current science has demonstrated infectivity potential only in the distal ileum of beef cattle.

Bearing in mind the US is believed to be an Office International des Epizooties (OIE) Minimal BSE Risk Country (but this is awaiting confirmation based on results of active surveillance for BSE in targeted populations conducted to standards advised by the International Committee and the OIE), in minimal disease countries the OIE requires no part of the intestine to be removed from animals passed fit for human consumption before being available for use in human food. In recognition of the available science on this issue, both FSIS and FDA have properly named the distal ileum as Specified Risk Material (SRM), and thus require that US product be removed and destroyed at the slaughterhouse as SRM. Only the distal ileum portion of the small intestine has demonstrated BSE infectivity, and the remaining portions of the small

intestine pose no known risk to human health. Figure 1[1] summarizes the results of the UK pathogenesis experiment and shows that there is intermittent infectivity present in the distal ileum from 6-18 months and 36-40 months post exposure. Thus, in order to stop amplification of BSE and limit exposure, we support a proposal that the distal ileum of cattle should be classified as SRM if from countries or zones which have moderate or high BSE risk.

The science of BSE in addition to the pathogenesis study comes from the study of infectivity and PrP-res (PrP^{Sc}) in bovine intestine from experimental BSE and natural BSE (Tables 1 and 2). The only place positive PrP^{Sc} staining was found in cattle intestine from experimental and natural cases of BSE was in the Peyer's patches and rarely in the myenteric plexus of the distal ileum, (Terry et al, 2003).

On the basis of this study, the only likely place in the intestine where PrP and infectivity can be demonstrated is the distal ileum. The ileum, which is readily identifiable, can be separated from the rest of the intestine with consistent accuracy and without cross contaminating the rest of the intestine. Thus, any remaining risk will be very low and even that would be reduced by the cleaning process, which is undertaken to remove the mucosa from the product for use as a casing.

Despite this scientific evidence however, the FSIS interim final and the FDA notice of advanced rulemaking implements a standard operating procedure that requires the removal and disposal of the entire small intestine from cattle of all ages.

B. Studies on other ruminant susceptibility to TSE, and non ruminant studies should not affect proper science-based decision-making concerning bovine susceptibility to BSE infectivity.

The available science is clear that there are distinct differences even among ruminant species as to infectivity of the BSE agent. For example, the attached Tables 1 and 2 shows the distinct differences between scrapie in sheep (ovine) and BSE in cattle (bovine). There is no evidence that BSE is present in sheep. However, this study (cite) demonstrates, for example, that should BSE be found to exist in sheep, then for risk animals the entire animal should be considered SRM.

Any studies involving non ruminants are even further removed from the science required for a determination on SRMs. A study cited to us by FDA officials for example, which looked at primates, deals solely with a primate-passaged agent in a primate, which is far removed from the situation in a bovine, which is a ruminant animal, and this study thus has no relevance to the question of SRM removal in bovines. (*Herzog C., Sales N., Etchegaray, N., Charbonnier A., Freire S., Dormont D., Deslys J-P., Lasmezas Cl., Tissue distribution of bovine spongiform encephalopathy agent in primates after intravenous or oral infection*, Lancet 2004; 363: pg 422-28)

C. The IRT recommendations for removal of the entire intestine were a part of overall recommendations on the need for short term aggressive action, not long term determinations on removal of SRM.

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[1] References providing supporting data for Figure 1 (Wells *et al)* and Tables 1 and 2 below (Fraser and Foster, Hadlow, *et al,* MAFF, Terry *et al,* Wells *et al,* and WHO) are listed at the end of this submission

The IRT recommendations were based upon the assumption that the US is a higher than minimal risk area, thus requiring aggressive surveillance and actions until such time as the US can be considered a minimal risk country or region. The US is a member of the OIE. The OIE recommends the removal of the intestine from moderate or high risk countries or regions, but does not require removal of any part of the intestine from provisionally free or minimal risk countries or zones. We believe that given the necessary information on the removal process for the distal ileum that this rule may be changed in the future to require only the removal of the distal ileum from moderate risk countries, instead of the entire intestine. However that is resolved -- in this instance, once the US can demonstrate that it is a provisionally free or minimal risk country, then no part of the intestine should be considered SRM. The US is now undertaking the testing and surveillance necessary to demonstrate its minimal risk classification, and the early results have shown no further evidence of any BSE in cattle in the US, while the only case detected thus far was in an imported animal. Even should a few positive cases be found, the US will likely be within the parameters of the minimal risk or provisionally free category under OIE criteria.

D. SRM removal when not scientifically justified will have negative consequences.

If the proposed rule is applied it will have the negative effect of increasing the quantity of SRM to destroy (as recommended by the International Committee) while not contributing to the improved protection of public health. Furthermore, if within a year or so the active surveillance results show that the US is truly a minimal BSE risk country, then the gap in collection and processing of US beef intestines to make natural casings will predictably cause significant damage to the North American natural casings industry, from which it may not recover.

E. The US and countries currently exporting beef casings already remove the distal ileum.

The casing industry does not consider the distal ileum to be usable as a casing, and to our knowledge, no portion of the distal ileum, or in fact the entire ileum is saved for use as a casing. The industry already has adopted the practice of removing and disposing of the distal ileum from all cattle at the time of slaughter. Thus, although not recommended by the OIE guidelines, a decision to impose a higher standard, a uniform rule requiring the removal of the distal ileum from all cattle, regardless of the BSE risk classification of the region of origin, could easily be complied with by BSE free and low risk countries which have sent this product to the US. In particular, major exporters of beef casings to the United States, such as Brazil, Argentina, Paraguay and Uruguay, already are able to certify the removal of the distal ileum upon request, using achievable and verifiable standards, and Australia has a regulation that requires the removal of the distal ileum from countries with a low incidence of BSE.

The interim final rule classifies only the distal ileum portion of the small intestine of cattle as specified risk material (SRM) to be prohibited from human consumption. Only the distal ileum portion of the small intestine has demonstrated BSE infectivity, and the remaining portions of the small intestine pose no known risk to human health. Despite this, the current rule implements a standard operating procedure that requires the removal and disposal of the entire small intestine from cattle of all ages. USDA should amend the rule to require the removal and disposal of only the distal ileum portion of the small intestine and approve a standard operating procedure to certify the effective removal and disposal of the distal ileum, while allowing the remaining portions of the small intestine to be cleaned and processed for human consumption.

The US Meat Export Federation has developed a detailed anatomical description of the beef small intestine that could be used to develop a model of certification for the removal and disposal of the distal ileum. [See **Attachment 1**, Photographs and definition of the bovine ileum] The ileum, which varies in average length from 15 to 24 inches depending on the age and size of the animal, is recognizable as the very straight portion of the intestine, with the proximal half beginning where the cranial mesenteric artery ends and the distal half terminating at the caecum. The portions of the beef small intestine used for casing, the duodenum and the proximal portion of jejunum, terminate at a point known as the "flange." Removal at the flange would include the entire ileum and the distal portion of the jejunum, which would measure a total of 36 to 72 inches in length depending on the age and size of the animal. This description was developed with full scientific oversight and has widespread support in the industry. This model easily could be adopted to certify the removal of the distal ileum from beef casings imported into the United States from BSE minimal risk regions.

This definition provides the basis for two readily verifiable standard operating procedures for the certified removal of the distal ileum. The first procedure begins with the removal of the small intestine from the abomasum. Then the small intestine is separated from the caecum at the ileocaecal orifice, and the ileum is separated from the jejunum at the flange. The resulting segment containing the ileum would measure 36 to 72 inches in length depending on the age and size of the animal. In an alternative procedure, following the removal of the small intestine from the abomasum, the small intestine remains attached to the caecum. Then separation is made at a point 36 to 80 inches from the caecum, leaving behind the remaining edible portions of the small intestine. Leaving the ileum attached to the caecum at this initial stage provides an easily verifiable point of reference for on-line inspectors. Finally, the 36 to 80 inch portion containing the ileum is separated from the caecum at the ileocaecal orifice, leaving the caecum and the large intestine for edible use.

Furthermore, FSIS already has approved a standard operating procedure, based on a procedure developed by a major exporter in the US industry, to certify the removal of the distal ileum from the remaining portions of the small intestine for beef casings intended for export. Prior to the diagnosis of a BSE-infected animal in the United States in December 2003, the Government of Japan, which requires the removal of the distal ileum from all beef casings, accepted the importation of beef casings from the United States on the basis of the US government-certified removal of the distal ileum. In particular, the procedure approved by FSIS requires the removal of at least 80 inches of the small intestine, as measured from the junction of the ileum and the caecum, in order to certify removal of the distal ileum.

NANCA and INSCA have prepared a CD that demonstrates the distinctive appearance of the bovine ileum. [See **Attachment 2**, Details of Beef Casing Production in Brazil: Eliminating the Distal Ileum (compact disc)] The entire ileum is embedded in the ruffle fat (see pages 2-5) and therefore, as a practice, is discarded with the fat. For the purpose of the CD, we have removed the ileum from the ruffle fat – a process that can be accomplished only by hand with scissors – to show its distinctively straight shape and irregular surface (see pages 9-10), which makes it clearly distinguishable from the portion of the small intestine saved for use as edible beef rounds. The distinct shape of the ileum means that an inspector easily could verify that the distal ileum has been removed (see pages 11-15). As demonstrated by these pictures, the ileum is not useable as a casing. It is never saved for such purpose, due in large part to the fact that the ileum has no curve and an irregular thick surface. Finally, in order to save this part of the animal as a distinct product, it would have to be removed from the ruffle fat using a time consuming and expensive process.

Due to the fact that the US government and the meat industry have available more than one acceptable standard to certify the removal of the distal ileum from the remaining portions of the small intestine, we see no need to require the removal and disposal of the entire small intestine. We note that the law in Canada identifies only the distal ileum as SRM, but also as a practice requires removal of the entire small intestine using a rationale similar to that used by the United States. Insofar as USDA wishes to implement rules consistent with those adopted by Canada, we believe that science-based changes to the US rule with achievable requirements, set in coordination and cooperation with CFIA, will lead to similar changes in the Canadian rule. As noted above, other exporting countries can also comply with a verifiable US Standard.

To ensure effective removal of the distal ileum, FSIS should approve a standard based on the available information, which we believe can be done quickly

II. Question 34, at page 42300, FSIS asks: *"Should FSIS provide an exemption for "BSE free" countries or countries with some other low-risk BSE designation?*

A. We recommend that any rule restricting the use and importation of beef intestines not apply to beef casings from regions which have reported no cases of BSE and/or which have clearly met the OIE criteria for the classification of BSE free, provisionally free or minimal risk countries or zones under OIE guidelines.

The FSIS interim final rule classifies the distal ileum portion of the small intestine of all cattle as SRM and requires the removal of the entire small intestine from cattle of all ages without regard to the BSE risk classification of the region of origin. To be in compliance with international standards adopted by the OIE, the interim final rule should be amended to remove restrictions on beef casings imported from regions which have had no reported cases of BSE and/or meet the OIE guidelines for countries or zones properly classified as free, provisionally free or minimal risk for BSE. To impose the same restrictions on low risk countries as are imposed on countries that are considered at moderate or above risk of BSE is not appropriate under international trade rules. An exemption for these BSE free or low risk countries or zones would coincide with the import regulations adopted by other trading countries, including the Government of Canada, with which the US rules are intended to conform.

Chapter 2.3.13 of the Terrestrial Animal Health Code of 2003, published by the OIE, recommends distinguishing between beef SRM (including intestines) required to be removed for trading purposes on the basis of the BSE risk classification of the region of origin. The OIE defines five risk categories (listed in decreasing order of risk): high risk, moderate risk, minimal risk, BSE provisionally free and BSE free.

Further, with respect to SRM removal, in Article 2.3.13.19, the OIE recommends banning the use of the entire intestine from cattle originating from high risk regions, banning the use of the distal ileum portion of the small intestine from cattle originating from moderate risk regions, and not restricting the use of any portion of the intestine from cattle originating from minimal risk, BSE provisionally free and BSE free regions. However, for trading purposes we understand that the BSE *Code* chapter for 2004 on BSE now recommends the removal of the entire intestine from cattle from countries with a high and moderate risk from BSE, but continues its recommendation that no part of the intestine need be removed from minimal risk, provisionally free or free regions. The US has to date had zero cases of BSE in native born animals, has adopted the OIE *Code* recommendations and by no stretch of the imagination can it be claimed definitely to be in a higher risk category than minimal risk. **Notwithstanding the actual categorization of the US and Canada in respect of BSE, the US and Canadian natural**

casings industry removes the whole of the ileum from cattle before processing the rest of the intestine into casings (see response to question 2), as do current BSE free countries which exported product to the US prior to implementation of the US regulation.

III. Question 35 at page 42300, FSIS asks: "If *FSIS were to exempt "BSE free" countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?"*

A. OIE Standards are the appropriate science based standards to use in determining BSE status of countries and/or regions.

Exporting countries that have met appropriate OIE criteria for BSE minimal or lower risk, should be treated in the manner set forth in the OIE guidelines. OIE BSE criteria have been developed with the input and support of the US and other major trading countries. For countries to set separate standards would not only be confusing but would detract from the goals of effective and science-based criteria. Furthermore, it would most likely lead to significant trade disruptions and restrictions implemented for non science based reasons. For these reasons, we strongly recommend that the OIE criteria be used in determining a country or region's BSE status.

IV. Question 36, at page 42300, FSIS asks: *"How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?"*

A. The US should use the OIE standards, and in cases where the OIE has completed its evaluation of a particular country or region, should accept that determination. In cases where the OIE has not made an evaluation, the US should make its evaluation based on those commonly accepted OIE international standards.

The OIE is currently evaluating countries requesting BSE status determinations and has, for example, already completed evaluations and made determinations of BSE free status for Argentina and Uruguay. Those countries should not, therefore, be treated the same way as countries that have reported cases of BSE. Further, other beef casing supplying countries (Brazil, Paraguay and Australia) have demonstrated their compliance with OIE guidelines and have provided significant information that should lead to rapid determinations by the US of free or provisionally free status.

We respectfully request that FSIS consider these comments when making its final rules. Please contact us if we can provide further information or assistance in connection with issues involving the safety of natural casings.

Sincerely,

Shirley A. Coffield

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